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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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7590	06/15/2004			
Santangelo Law Offices, P.C. Third Floor 125 South Howes Fort Collins, CO 80521			EXAMINER MYERS, CARLA J	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/879,480

Applicant(s)

WHITTIER ET AL.

Examiner

Carla Myers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to the amendment filed April 5, 2004. Claims 1-27 have been cancelled. Claims 28-50 were filed in the response of April 5, 2004. Applicants amendments and arguments set forth in the response have been fully considered, but are not persuasive to overcome all grounds of rejection. All rejections not reiterated herein are hereby withdrawn. This action is made final.

THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY
APPLICANT'S AMENDMENTS TO THE CLAIMS

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 28-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The specification as originally filed does not provide basis for newly added claims 28-50. Specifically, the specification does not provide basis for the concepts of: a) methods of managing a plurality of nonhuman female mammals for increased "biological efficiency" in a commercial environment; b) estimating "biological costs" and "biological gains"; c) the broad practice of "utilizing" estimates of economic costs,

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biological costs, economic gains and biological gains; d) utilizing a time interval wherein the time interval results in a net economic gain and a net biological gain; and e) harvesting the nonhuman female mammals upon expiration of a time interval that results in net economic gain and net biological gain.

The specification as originally filed provides basis for the general concept of a method of managing nonhuman female mammals and in particular provides support for methods which comprise inducing early puberty in a female nonhuman mammal, fertilizing at least one egg in said mammal using a plurality of sex-sorted spermatozoa, producing offspring from said mammal, and harvesting the mammals following the birth of offspring. At pages 12-13, the specification discusses an Integrated Herd Management System (IS) that incorporates reproductive factors such as inducing early puberty, synchronizing estrous, use of sex sorted sperm, and early weaning of offspring. At page 4, the specification teaches that one aspect of the invention is to increase the percentage of female animals available to expand the herd using sex-sorted sperm. It is stated that integrating early-weaning, induction of early puberty and sexed-sorted semen into a single calf heifer system will increase the value of non-replacement heifers and increase profitability. Additionally, the specification (e.g., page 27 and 49) provides an economic analysis of the total income and expenditures recorded per year. Gross revenue/loss and net revenue/loss were calculated. These calculations took into consideration, for example, pregnancy rates, calf survival, feed costs, breeding costs, pasture lease costs, health costs and market price. The specification (page 32) states that "simulations were conducted to evaluate the effect of pregnancy rate and increased

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calf survival on profitability.” Additionally, the specification (beginning at page 43) teaches evaluating carcass characteristics. At page 12, the specification states that “(w)hile Figure 7 provides a specific time line for beef cattle embodiment of the herd management invention, it is understood that (it) is illustrative of the broad variety of species of mammal that can be managed in a similar fashion.” However, the cost analysis provided in the specification was performed with respect to the management of bovine.

The teachings in the specification do not provide basis for the specific embodiments set forth in the present claims. The specification teaches estimating the economic costs of inducing early puberty and discusses certain health effects and fertilization effects associated with inducing early puberty. The specification also discusses estimating the economic gain of harvesting the mammals that were bred. The specification does not teach the broader concepts of utilizing, in any manner, estimates of an economic cost of inducing early puberty, estimates of a biological cost of inducing early puberty, estimates of a economic gain of harvesting substantially all female mammals that were bred, and estimates of a biological gain of harvesting substantially all female mammals that were bred. The specification teaches the use of estimates of economic cost and gain to evaluate the integrated herd management system. There are no teachings in the specification as to how to use the estimates for any other purpose. The specification teaches the time interval between inducing early puberty and harvesting the mammals used for breeding (see, e.g., Figure 7). However, the specification does not teach the specific embodiment of determining a time interval that

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begins at inducing early puberty and ends at harvesting the mammal used for breeding, wherein the time interval results in a net economic gain and a net biological gain and does not teach the step of harvesting the female mammals upon the expiration of this time interval. The teachings in the specification of specific time intervals between inducing early puberty and harvesting were not determined based on a time interval that results in a net economic gain and a net biological gain. Also, the specification does not teach applying these specific teachings of the determining a time interval based on net economic gain and net biological gain to all mammals. The specification as originally filed does not specifically refer to or define "biological gain" or "biological efficiency." While some of the parameters discussed in the specification may fall into the categories of "biological gain" and "biological efficiency," these categories encompass numerous parameters which are not discussed or analyzed in the present specification. It is noted that claims 28, 45 and 47-50 are inclusive of methods of managing any female mammal, claims 41-43 are inclusive of methods of managing female equine, and claims 44 and 46 are directed to methods of managing female ovine, porcine and goats. The examples provided in the specification are limited to the biological attributes of bovine. There are no clear teachings in the specification as to what is intended to be encompassed by the phrases "biological gain" and "biological efficiency" with respect to bovine, equine, ovine, porcine, goats or any other mammal. The attributes to be used for estimating the biological cost of inducing early puberty and for estimating biological gain for harvesting bred mammals are not clearly defined in the specification. The replacement system set forth in the specification is described with respect to its

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application to bovine. It is unclear as to how this replacement system similarly applies directly to mammals that are not bred as a food source. While the specification states at page 12, that the system is applicable to a variety of species of mammal "that can be managed in a similar fashion," animals such as equine are not typically managed in a system in which the animal that was just bred is replaced with its offspring. Similarly, it is not conventional to manage other mammals such as monkeys, dolphins, elephants, lions, etc, in a system in which each time the mammal gives birth to an offspring, that mammal is slaughtered. The specification does not describe how one evaluates the biological cost of inducing early pregnancy or the biological gain of harvesting such mammals. Accordingly, the specification does not provide basis for the broadly claimed concept of estimating biological cost or biological gain of managing any female mammal for increased biological efficiency and does not provide basis for the concept of determining a time interval based on a net biological gain and then harvesting the mammal upon the expiration of the time interval.

In the amendment/response filed April 5, 2004, Applicants do not point to any particular teachings in the specification as providing support for the newly added claims. If Applicants traverse this rejection, they should point to specific pages / lines of the specification as providing support for each embodiment of the claimed invention.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28-50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of producing bovine offspring wherein the methods comprise inseminating a female bovine with an insemination sample having a plurality of spermatozoa wherein the spermatozoa have been purified to the extent that up to 90% of the spermatozoa have X-bearing and while the prior art (Buchanan 2000) has enabled methods of producing equine offspring wherein the methods comprise inseminating a female equine with an insemination sample having a plurality of spermatozoa wherein up to 90% of the spermatozoa have an X chromosome, and while the prior art (Rens US Patent No. 5,985,216, issued November 16, 1999) has enabled methods of producing porcine offspring wherein the methods comprise inseminating a female porcine with an insemination sample having a plurality of spermatozoa wherein up to 92% of the spermatozoa have a Y chromosome, does not reasonably provide enablement for methods of managing any nonhuman female mammal for increased economic and biological efficiency comprising utilizing an estimate of economic cost and biological cost of inducing early puberty, utilizing an estimate of economic gain and biological gain of harvesting bred mammals, determining a time interval that begins with inducing early puberty and ends with harvesting wherein the time interval results in a net economic gain and net biological gain, inducing early puberty in said any nonhuman female mammal, fertilizing at least one egg derived from the female mammal using sex-sorted spermatozoa, producing offspring, and harvesting substantially all of the bred nonhuman female mammals upon the expiration of the determined time interval. The specification does not enable any person skilled in the art

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to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The following factors have been considered in formulating this rejection (*In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988): the breadth of the claims, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, the amount of direction or guidance presented, the presence or absence of working examples of the invention and the quantity of experimentation necessary.

The claims are drawn broadly to methods of managing a plurality of nonhuman female mammals for increased economic and biological efficiency in a commercial environment. The claims include the steps of inducing early puberty in the mammal, fertilizing the mammal with sex-sorted spermatozoa, producing offspring and harvesting said mammals. The claims further comprise estimating the economic cost and biological cost of inducing early puberty and the economic gain and biological gain of harvesting the mammals and determining a time interval that begins with inducing early pregnancy and ends with harvesting mammals wherein the time interval results in a net economic gain and a net biological gain. Additionally, the claims encompass the use of sex-sorted spermatozoa samples that include at least 90% of spermatozoa that have the same sex determination characteristic.

Case law has established that "(t)o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright* 990 F.2d 1557, 1561. *In re*

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Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) it was determined that "(t)he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art". Furthermore, the Court in *Genetech Inc. v Novo Nordisk* 42 USPQ2d 1001 held that "(I)t is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement". In the instant case, specification has not adequately taught one of skill in the art how to practice methods of enriching spermatozoa to purities of 100% in bovine mammals or to purities of 90% or greater in all animals for the following reasons.

The specification at page 6 states that the claimed invention is not intended to be limited to bovine animals. Rather, the claimed invention is applicable "to a variety of species of mammal including, but not limited to, bovids, equids, ovids, canids, goats or swine, as well as less commonly known animals such as elephants, zebra, camels, or kudu...As such, the examples provided are not intended to limit the description of the invention to the management of any particular specie(s) of mammal(s)." Accordingly, Applicant's claims are intended to include the management of any nonhuman female mammal population by inducing early puberty, fertilizing at least one egg of the mammal with sex-sorted sperm, producing offspring and harvesting the female mammals that were used for breeding. The single-calf heifer system is known in the art. However, this system of harvesting each mammal that was used for reproductive purposes is not known in the art as a means for managing all nonhuman mammal populations. The teachings in the specification are directly specifically to the management of bovine. The

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specification does not provide any specific teachings of how to apply the claimed integrated herd management system to any nonhuman mammal.

In particular, Applicants have not adequately taught how to induce early puberty in any nonhuman female mammal. While the specification states that "Diet is an effective tool to induce puberty" (see page 2), it is not clear as to whether this statement is intended to refer only to bovines. There are no teachings in the specification as to the use of controlling diet as a means of inducing early puberty in other types of female mammals. The specification does not teach that the methods used for inducing early puberty in bovine are also applicable to inducing early puberty in equine, ovine, porcine, goats, chickens, dogs, elephants, gorillas etc. The specification does not exemplify inducing early puberty in non-bovine animals. In the absence of any specific guidance from the specification as to how one would induce early puberty in additional species of mammals then use this female effectively for reproductive purposes, undue experimentation would be required to practice this aspect of the claimed invention.

Secondly, the specification does not provide sufficient guidance as to how to apply the claimed method to the management of any nonhuman female mammal for increased economic and biological efficiency. The specification (e.g., page 12) teaches that the claimed system is applicable to a variety of species of mammal "that can be managed in a similar fashion." However, the claims broadly encompass the use of any nonhuman mammal and are not limited to animals that are conventionally managed in a system in which each animal used for breeding is slaughtered after the birth of their offspring. For example, equine are not typically managed in a replacement system in

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which the animal that was just bred is replaced with its offspring. Similarly, it is not conventional to manage other mammals such as monkeys, dolphins, elephants, pandas, etc, in a system in which each time the animal gives birth to an offspring, that animal is slaughtered. The specification does provide sufficient guidance to enable one skilled in the art to effectively manage such mammals in a manner that would allow for inducing early puberty and harvesting the animals at a time interval that results in a net economic gain and net biological gain. The specification does not define what is encompassed by "biological efficiency," "biological cost" and "biological gain" as these phrases are applied to any nonhuman mammal. Further, the specification does not describe how one evaluates the biological cost of inducing early pregnancy or the biological gain of harvesting such mammals. For example, considering the species of pandas, it is unpredictable as to whether early puberty could be induced in the panda and it is unpredictable as to what methodology would be used to induce early puberty; it is unpredictable as to what criteria one would use to estimate the biological cost of inducing early puberty; it is unpredictable as to what parameters one would utilize to estimate the biological gain of harvesting panda's that are used in the breeding process; it is unpredictable as to what would be the efficiency of fertilization and the production of offspring in puberty-induced panda's fertilized with sex-sorted sperm; and it is unpredictable as to what time interval would be required to fulfill the criteria that the time interval results in a net economic gain and a net biological gain. Applicants have not established that, for a representative number of species encompassed by the claimed invention, a time interval between inducing early puberty and harvesting the mammals

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does in fact exist whereby the time interval results in a net economic gain and a net biological gain.

Further, the teachings in the specification support the unpredictability of determining a time interval that results in net economic gain and net biological gain. For example, the specification (page 50) teaches that the IS was not more profitable than traditional management systems of non-replacement heifers. Only by using a simulation in which pregnancy rates were 58% and calf survival was increased, did the IS system become more economically valuable than the TMS. Based on the teachings in the specification, it is unclear as to whether calf survival rates could be increased to those used in the simulation under the conditions set forth in the claims in which the calves are obtained from mothers in which early puberty was induced and in which fertilization was performed using sex-sorted sperm. Importantly, the specification at page 51 concludes that "The simulations (Table 18) showed that under the assumptions, the IS can be profitable above the TMS. The most appropriate figures to assess the system are those associated with 80% pregnancy rate. This rate is the most acceptable pregnancy rate and could probably be achieved with the IS with further development and research into the project." Accordingly, in the absence of specific guidance as to the criteria that could be used to determine the biological cost and gain of inducing early puberty and harvesting any nonhuman female mammal and in view of the unpredictability in obtaining the required pregnancy and offspring survival rates, undue experimentation would be required for the skilled artisan to practice the claimed method

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of managing a plurality of any nonhuman female mammal for increased economic and biological efficiency.

Additionally, the ability to sort sperm from any nonhuman mammal on the basis of a sex determination characteristic such that the resulting sample can be used for fertilization to reproducibly generate offspring in which 90% or more of the offspring are female is highly unpredictable. This unpredictability is exemplified by the results set forth in the specification. In particular, pages 40-41 of the specification states:

"Eleven of 16 (69%) calves conceived from semen sorted for X-chromosome were female and all three calves conceived from non-sexed semen were bulls (100%), whereas the only female born to natural serve was female (100%). Seidel et al. (87) reported that 86% of calves conceived from sexed semen are of the desired sex. The result of this data set of 69% of calves conceived from sexed semen were of desired sex, is not an adequate replication of their study as too few individuals were used. The low percent of desired sex was not expected as the true percent of X-chromosome sperm varied from 86-92% for the batches of semen used in the study."

The specification does not provide any examples in which spermatozoa were sorted to rates above 86-92% and fails to teach how the methodology set forth within the specification could be modified to achieve the production of animals in which more than 69% of the animals of one "desired" sex. The prior art of Rens (US Patent 5,985,216, issued 1999) does teach that bovine sperm can be sorted to purities of about 90%. Rens also teaches that under some conditions, porcine sperm could be sorted to a purity of 92% for sperm bearing the Y chromosome. In addition, Buchanan (April 2000, page 1337) teaches methods for sorting equine sperm wherein the sperm were successfully sorted to a purity of 90% for sperm bearing the X chromosome and to 84%

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for sperm bearing the Y chromosome. However, there is no specific guidance provided in the specification for how one may accomplish the sexing of sperm to achieve purity rates of 95%, 99% or 100% in bovine, equine, ovine, porcine and goats. It is unpredictable as to whether one of skill in the art could sort sperm from these mammals at purity rates of above 90% and generate populations of mammals in which 90% or more of the offspring are female. The unpredictability of sorting sperm to high levels of purity, including purity levels above 90% is supported by the teachings in the art. For example, Fugger (1999; cited in the IDS of 6/12/01) teach that using the most current techniques, human sperm cells can be separated to provide samples containing on average 88% enrichment for X-bearing sperm and 69% enrichment for Y-bearing sperm (see page 1439). Fugger goes on to state that :

"Human sperm cells present unique characteristics that affect the ability to detect and separate X and Y sperm by flow cytometry. The current flow technology appears to be most efficient with sperm cells that have a substantial difference in total DNA, are relatively homogeneous with respect to physical shape and cellular morphology, and are more paddle shaped to take advantage of flow-induced orientation before fluorescence detection. Most human sperm, however, are heterogeneous, vary substantially within and between individuals, are oval in shape, vary in the magnitude of difference in DNA content between X and Y chromosomes due to individual variation in size of the Y chromosome, and contain a relatively small 2.8% difference in total DNA content compared to >3.5% for most domestic animals."

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Additionally, Johnson (1992, page 13; cited in the IDS of 6/12/01) teach the difference in DNA content between X and y chromosome bearing sperm for several organisms, including turkey (0% difference), human (2.9% difference) and rabbit (3% difference). Johnson also reports that rabbit sperm were sorted to purities of 86% for X-chromosome bearing sperm and 81% for Y-chromosome bearing sperm.

However, there are no teachings in the prior art as to how to overcome the problems associated with a lack of difference in the DNA content between X and Y-chromosome bearing sperm or the challenges imposed by the shape, morphology and heterogeneity of sperm. The specification and prior art do not appear to exemplify any methods in which sperm from are reproducibly purified to sufficient purity to generate populations of mammals comprising at least 90% of female offspring. The specification does not provide sufficient guidance as to how to sort sperm from equine, ovine and goats to purity levels of above 90%. It is unpredictable as to what methodologies should be employed to achieve these high purity levels and to produce offspring in which 90% or more of the offspring are female.

Accordingly, in view of the unpredictability in the art and the lack of specific guidance provided in the specification, undue experimentation would be required to practice the invention as it is broadly claimed.

RESPONSE TO ARGUMENTS:

In the response filed April 5, 2004, Applicants traversed the previous grounds of rejection. Applicants state claim 46 is now limited to bovine, equine, porcine, ovine and goats. Additionally, Applicant's rely on the 132 Declaration of Dr. Schenk as providing

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evidence that the sperm from these mammals could be sorted to purities of at least 90%. The Declaration of Dr. Schenk has been fully considered. However, the declaration is not persuasive because the declaration is a statement of opinion and does not contain any evidence to support these opinions. The Declaration states that "it is now and was at the time the application was initially filed on June 12, 2000, known that one could achieve levels of substantially all female offspring selected from the group consisting of...at least 90% female offspring. While additional statements could be made, it may suffice to simply state that I believe the stated percentages of success were not unpredictable in stated non-human mammals, namely bovines, equids, ovines, porcines, and goats." The declaration does not provide any factual evidence or scientific arguments / reasoning to corroborate the conclusions drawn therein. Further, the statements in the Declaration are vague and it is unclear as to whether the Declaration takes into consideration the fact that the invention encompasses producing offspring in which 95%, 99% or 100% of the offspring are female. Accordingly, the Declaration of Dr. Schenk is not sufficient to overcome the present grounds of rejection.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 28-50 are indefinite over the recitations of "biological efficiency," "biological cost of inducing early puberty" and "biological gain of harvesting." These

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phrases are not clearly defined in the specification and there is no art recognized definition for these phrases as they apply to bovine, equine, ovine, porcine, goats or all other mammals. For example, would the biological cost of inducing early puberty in an equine encompass the effect of early puberty on the animal's athletic performance? Would the biological cost of inducing early puberty in a goat encompass analyzing the effect of early puberty on milk production? Or is the biological cost limited to the effect of early puberty on fertility and health of the mammal? In the absence of a complete and clear definition as to what is intended to be encompassed by these phrases, one of skill in the art cannot determine the meets and bounds of the claimed invention.

Claims 28-50 are indefinite over the recitations of "utilizing." The claims do not clarify how one utilizes, e.g., an estimate of an economic cost. That is, for what purpose does one utilize an estimate of an economic cost. It is unclear as to what is intended to be encompassed by each step of "utilizing" and it is unclear as to how these recitations are intended to serve as active process steps within the claimed invention.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)-272-0782.

Papers related to this application may be faxed to Group 1634 via the PTO Fax Center using the fax number (703)-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Carla Myers
June 9, 2004


CARLA J. MYERS
PRIMARY EXAMINER